K031653

JUN 2 0 2003

Premarket Notification 510(k) Summary
As required by section 807.92
Datex-Ohmeda HMEF 750

GENERAL COMPANY INFORMATION as required by 807.92(a)(1)

COMPANY NAME/ADDRESS/PHONE/FAX:

Datex-Ohmeda
86 Pilgrim Road
Needham, MA 02492 USA
Tel: 781-449-8685
Fax: 781-433-1344

NAME OF CONTACT:

Mr. Joel Kent

DATE:

May 19, 2002

DEVICE NAME as required by 807.92(a)(2)

TRADE NAME:

Datex-Ohmeda HMEF 750

COMMON NAME:

Disposable Heat and Moisture Exchanger and Bacteria/Viral Filter

CLASSIFICATION NAME:

The following Class II classification appears applicable:

CAH Breathing Circuit Bacterial Filter 868.5260

NAME OF LEGALLY MARKETED DEVICE FOR WHICH A CLAIM OF SUBSTANTIAL EQUIVALENCE IS MADE as required by 807.92(a)(3)

The Datex-Ohmeda HMEF 750 is substantially equivalent in safety and effectiveness to the legally marketed (predicate) Datex-Ohmeda HMEF500 (K021265).

DEVICE DESCRIPTION as required by 807.92(a)(4)

The intended use and indications for use for the modified device are the same as the predicate.

There has been no change to the fundamental scientific technology from the predicate.

The HMEF 750 incorporates a hygroscopically treated HME media and electrostatic filter media into a housing made of translucent plastic.

Dimensions and Materials
- Diameter: 62 mm
- Length: 64 mm
- Housing: PP Polypropylene
- HME-element: PU Polyurethane impregnated with calcium chloride CaCl2
- Filter: PP and acrylic fibers

Filtration efficiency:
- Filtration efficiency viral 99.998 %
- Filtration efficiency bacterial 99.9999 %

The HMEF 750 is for use in small adult and pediatric patients in the hospital, ICU, anesthesia, respiratory therapy, during transport and with resuscitators.

It incorporates standard fittings for-
- 15 mm ID x 22 mm OD fitting to connect to the endotracheal tube or face mask
- 15 mm OD x 22 mm ID fitting to connect to the breathing circuit Y-piece
- A gas sampling port – female luer port with cap to allow sampling of expired CO2 gases

The modifications to the device are:

The Datex-Ohmeda HMEF 750 has the following differences when compared to the Datex-Ohmeda HMEF 500 predicate device:

The devices differ in length, weight, dead space, moisture output, moisture loss, breathing resistance and maximum tidal volume

The main differences between the Datex-Ohmeda HMEF 750 and the predicate Datex-Ohmeda HMEF500 (K021265) are due to fact that the length of the Datex-Ohmeda HMEF 750 is shorter and the width of the HMEF 750 is wider than the Datex-Ohmeda HMEF500 (K021265). This makes the dead space of the HMEF 750 little bit larger than HMEF500 but gives much lower breathing resistances and better moisture output. The HMEF 750 can be used larger patient than predicate HMEF 500.

The predicate HMEF 500 has a bacterial filtration efficiency (BFE) of 99.999% and the HMEF 750 has BFE of 99.9999%.
The predicate HMEF 500 has the Viral Filtration efficiency (VFE) of 99.98% and the HMEF 750 has VFE of 99.998%.

The changes in the labels and instructions for use were made to add the specifications and name of the new device to the IFU. No changes in the warnings, cautions or contraindications have been made.

INTENDED USE as required by 807.92(a)(5)

Indication for use: The HMEF 750 is a disposable single–use device indicated for patients who require humidification during the delivery of ventilator gases and provide filtration for reducing possible cross contamination between patient and equipment. The HMEF 750 is for use in hospital, ICU, anesthesia, respiratory therapy, during transport and with resuscitators. The device can be used on adult and pediatric patients. The device is indicated for use by qualified medical personnel only

SUMMARY OF TECHNOLOGICAL CHARACTERITICS OF DEVICE COMPARED TO THE PREDICATE DEVICE as required by 807.92(a)(6)

The Datex-Ohmeda HMEF 750 is substantially equivalent in safety and effectiveness to the legally marketed (predicate) Datex-Ohmeda HMEF500 (K021265).
The Datex-Ohmeda HMEF 750 has the following similarities to the Datex-Ohmeda HMEF 500 predicate device:
-have the same indicated use
-have the same fundamental scientific technology and use the same operating principle
-are manufactured using the same processes
-constructed of identical materials
-Both the HMEF 750 and predicate HMEF 500 give efficient protection against transfer of bacteria / viruses between patients, personnel and equipment

The Datex-Ohmeda HMEF 750 has the following differences when compared to the Datex-Ohmeda HMEF 500 predicate device:
-The devices differ in length, weight, dead space
-Filtration efficiency against virus
-Filtration efficiency against bacteria
-The devices differ in Moisture output, Moisture loss, Breathing resistance and Maximum Tidal Volume

The main differences between the Datex-Ohmeda HMEF 750 and the predicate Datex-Ohmeda HMEF 500 (K021265) are due to fact that the length of the Datex-Ohmeda HMEF 750 is shorter and the width of the HMEF 750 is wider than the Datex-Ohmeda HMEF 500 (K021265). This makes the dead space of the HMEF 750 little bit larger than HMEF 500 but gives much lower breathing resistances and better moisture output.

The predicate HMEF 500 has a bacterial filtration efficiency (BFE) of 99.999% and the HMEF 750 has BFE of 99.9999%.
The predicate HMEF 500 has the Viral Filtration efficiency (VFE) of 99.98% and the HMEF 750 has VFE of 99.998%.

In summary, the Datex-Ohmeda HMEF 750, described in this submission is substantially equivalent to the predicate HMEF 500 (K021265).

SUMMARY OF NONCLINICAL TESTING FOR THE DEVICE and CONCLUSIONS as required by 807.92(b)(1)(3)

The Datex-Ohmeda HMEF 750 complies with the safety standards below and is therefore safe and effective for the intended use. The device has been thoroughly tested through validation and verification of specifications. Verification of compliance with the following mandatory and voluntary standards has been made:

- ISO 9360:2000
- ISO 5356-1:1996
- ISO 594-1:1986
- ISO 594-2:1998
- EN 980:1996
- EN 1041:1998
- EN 13014
- ASTM F 1054-8721

Conclusion:
The summary above shows that there are no new questions of safety and effectiveness for the Datex-Ohmeda HMEF 750 as compared to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 0 2003

Mr. Joel C. Kent
Manager, Quality Assurance and Regulatory Affairs
Datex Ohmeda
86 Pilgrim Road
Needham, MA 02492

Re: K031653
Trade/Device Name: Datex-Ohmeda HMEF 750
Regulation Number: 21 CFR 868.5260
Regulation Name: Breathing Circuit Bacterial Filter
Regulatory Class: II
Product Code: CAH
Dated: May 27, 2003
Received: May 28, 2003

Dear Mr. Kent:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

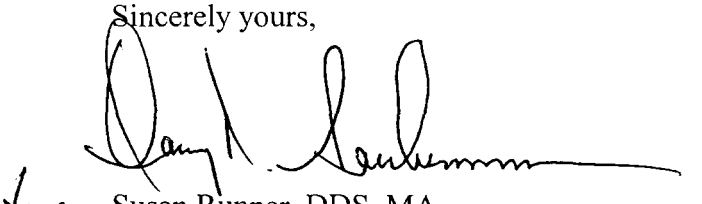
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,



for Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K031653

Device Name: Datex-Ohmeda HMEF 750

The HMEF 750 is a disposable single-use device indicated for patients who require humidification during the delivery of ventilator gases and provide filtration for reducing possible cross contamination between patient and equipment. The HMEF 750 is for use in hospital, ICU, anesthesia, respiratory therapy, during transport and with resuscitators. The device can be used on adult and pediatric patients. The device is indicated for use by qualified medical personnel only.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

6/20/03

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K031653